Remarks

Priority Documents

The Office Action notes that only some of the certified copies of priority documents were received, but does not indicate which are missing. Please indicate which documents are missing so that Applicants can provide the missing documents with the next response.

Objections to the Specification

The specification is amended to indicate trademarks, to delete the hyperlink on page 63, and to delete the reference to Figure 8d (Figure 8 contains only Figures 8a, 8b, and 8c).

Objections to the Drawings

Replacement Figures 7b and 9b accompany this amendment. The replacement drawings do not add new matter.

Rejection Under 35 U.S.C. § 112 ¶ 1 (written description)

Claims 7, 13, and 23-25 are rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement. To advance prosecution, the claims are amended to delete the term "oligonucleotides comprising CpG motifs." Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 1 (enablement)

Claims 1, 3-8, 10, and 12-16 are rejected under 35 U.S.C. § 112 ¶ 1 as not enabled for their full scope. Applicants respectfully traverse the rejection.

The enablement requirement of 35 U.S.C. § 112, first paragraph states that a patent specification must teach a person skilled in the relevant art how to make and use the invention claimed. Whether a specification enables a claimed invention is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). The proper standard for determining whether the present specification meets the enablement requirement is whether any experimentation which may be needed to make and use the compositions of claims 1, 3-8, 10, and 12-16 is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

It is hornbook law that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). The requirement that the patent holder enable the "full scope" of the claimed invention has never been interpreted to require the enablement of every embodiment within the scope of the claims. *See, e.g., In re Wright*, 999 F.2d 1557, 1563 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) ("It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art.") (citation omitted).

The Examiner contends that the specification enables an immunogenic composition comprising the five *C. trachomatis* antigens recited in claim 1 but does not enable "a vaccine composition comprising a combination of C. trachomatis antigens that is less than 5 antigens." Claim 16 is the only claim of the rejected claims that is directed to a vaccine composition. Claims 1, 3-8, 10, and 12-15 are directed to immunogenic compositions. The examiner has not

provided any reason why the specification does not enable immunogenic compositions comprising fewer than five of the recited *C. trachomatis* antigens. In fact, the evidence is to the contrary. For example, on page 80, last full paragraph, the specification teaches that CT398 "yielded the best neutralization titre in this study." This disclosure provides evidence that CT398 on its own is immunogenic.

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided in the specification. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). The Examiner must explain why she doubts the statements in the specification's supporting disclosure and also must support her assertions "with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971). The Examiner has not met this burden with respect to either immunogenic or vaccine compositions.

The Examiner cites Igietseme to support the rejection. Igietseme was published in 2000 and did not have the benefit of the present specification, which specifically teaches compositions comprising combinations of two or more of a recited group of *C. trachomatis* antigens. Igietseme is therefore not relevant to whether the present specification enables either immunogenic or vaccine compositions comprising fewer than five *C. trachomatis* antigens.

The Examiner also states on page 12 that "no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary." Again, the burden of establishing that undue experimentation would be required to practice the claimed invention belongs to the Examiner, not to the Applicants. The Examiner provides no other support for the rejection and therefore has not established a *prima facie* case that claims 1, 3-8, 10, and 12-16 are not enabled. Please withdraw the rejection.

Rejection of Claims 1, 3-8, 10, 12-16, and 22-25 Under 35 U.S.C. § 102(a)

Independent claims 1-3, 10, 12-16, and 22-25 are rejected under 35 U.S.C. § 102(a) as anticipated by Grandi (WO 2003/049762). Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Examiner cites Grandi as disclosing the following subject matter:

> Grandi et al discloses polypeptides derived from Chlamydia trachomatis that are suitable for vaccine preparation, antigens and immunogens suitable for use in vaccine development (abstract; p. 1; claims). Grandi et al discloses that the compositions can comprise two or more proteins, Chlamydia trachomatis antigens (p. 7; claims). Grandi et al specifically disclose among others, CT398 (SEQ ID NO: 111), LcrE (SEQ ID NO: 61), HtrA (SEQ ID NO: 229), ArtJ (SEQ ID NO: 105), PepA (SEQ ID NO: 71), DnaK (SEQ ID NO: 107) and CT547 (examples; Table 1; claims). Grandi discloses the use of adjuvants in order to enhance immunogenicity (p. 7; pp22-25).

The Examiner also states that "the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art."

The rejected claims are not directed to proteins; they are directed to immunogenic compositions (claims 1-3, 10, 12-15, and 22-25) and to vaccines (claim 16) that comprise particular combinations of *C. trachomatis* antigens. Each of independent claims 1, 8, 16, and 22 requires a combination of *C. trachomatis* antigens selected from a particular group:

- claims 1 and 22 require that the combination of *C trachomatis* antigens be selected from a particular group of five *C. trachomatis* antigens: of PepA, LcrE, ArtJ, DnaK and CT398;

- claim 8 requires that the combination of *C. trachomatis* antigens must be selected from a particular group of 13 particular *C. trachomatis* antigens: PepA, LcrE, ArtJ, DnaK, CT398, OmpH-like, L7/L12, OmcA, AtoS, CT547, Enolase, HtrA, and MurG; and
- claim 16 requires that the combination be selected from the group of five or the group of eight particular *C. trachomatis* antigens.

It is black letter law that a reference does not anticipate a claim unless the reference discloses all of the limitations of the claim "arranged or combined in the same way as recited in the claim." See *Net MoneyIN, Inc. v. VeriSign, Inc.,* 545 F.3d 1359, 1371 (Fed. Cir. 2008) ("unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipated under 35 U.S.C. § 102."). Grandi does not disclose compositions comprising two (or more) antigens selected from either of the recited groups of antigens. Because Grandi does not disclose each element of the rejected independent claims "arranged or combined in the same way," Grandi does not anticipate any of claims 1-3, 10, 12-16, and 22-25.

Please withdraw the rejection.

Respectfully submitted,

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